1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in ... [the] claim." Manual of Patent Examining Procedure (MPEP) § 2131 (8th ed., August 2001); and *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Davis discloses the use of ziprasidone. It does not teach or suggest the use of ziprasidone metabolites. Indeed, it is admitted on page 3 of the Office Action that Davis does not teach ziprasidone metabolites. As the Examiner is aware, the presently claimed invention is directed to the use of ziprasidone metabolites.

Because Davis does not disclose metabolites of ziprasidone or their administration to patents, Applicants respectfully submit that Davis does not disclose "each and every element as set forth in the claim of the present invention." Accordingly, Applicants respectfully submit that the present invention cannot be anticipated by Davis. For this reason, Applicants respectfully request that the rejection of claims 1-4 and 6-9 over Davis be withdrawn.

II. The Rejection Under 35 U.S.C. § 103 Should be Withdrawn

On pages 2-4 of the Office Action, claims 5 and 10-15 are rejected under 35 U.S.C. § 103 as allegedly obvious over Davis in view of Lowe *et al.*, U.S. Patent No. 4,831,031 ("Lowe") and Allen *et al.*, U.S. Patent No. 5,312,925 ("Allen"). This rejection is respectfully traversed.

As the Examiner is well aware, three basic criteria must be met in order to establish a *prima facie* case of obviousness: first, there must be some suggestion or motivation to modify or combine the cited references; second, there must be a reasonable expectation of success; and third, the prior art references must teach or suggest all the claim limitations. MPEP § 2143. These criteria must be satisfied with factual and objective evidence found in the prior art. An examiner's conclusory statements cannot form a basis for a *prima facie* case of obviousness. *See, In re Sang-Su Lee*, 277 F.3d 1338, 1343-4 (Fed. Cir. 2002). For example, an examiner can only satisfy the burden of showing the obviousness of a combination of references by "showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references." *Id.* at 1343 (quoting *In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992)) (emphasis added).

Applicants respectfully submit that the Examiner has not shown that, prior to this invention, those of ordinary skill in the art would have been motivated to combine Davis, Lowe and Allen. Even if such a motivation did exist, however, Applicants respectfully submit that the combination of cited art does not disclose all of the limitations recited by the pending claims.

As discussed above, Davis does not disclose or even suggest the use of ziprasidone metabolites. Indeed, on page 3 of the Office Action, it is admitted that Davis "does not specifically teach ziprasidone metabolites, amounts (i.e., dosage), [and] routes of administration." Similarly, neither of the other cited references disclose or suggest the use of ziprasidone metabolites. As the Examiner correctly points out on pages 3-4 of the Office Action, Lowe discloses ziprasidones and their salts, and their uses in the treatment of neuroleptic diseases. *See, e.g.*, Lowe, col. 1, line 25 to col. 2, line 24. Allen teaches ziprasidone hydrochloride and its employment in treating neuroleptic diseases. *See, e.g.*, Allen, col. 1, line 32 to col. 2, line 68. None of the cited references, however, either alone or in combination, teach or suggest ziprasidone metabolites, much less their use in the methods recited by the pending claims.

Nonetheless, the Examiner states that it would have been obvious to one of ordinary skilled in the art to employ "ziprasidone or any of its known salts or metabolites" in a method of treating neuroleptic disorders. (Page 4, paragraph 2 of the Office Action). He further alleges that one of ordinary skilled in the art would have been motivated to employ "ziprasidone or any of its known salts or metabolites" in a method of treating neuroleptic disorders because ziprasidone in general and ziprasidone hydrochloride are known neuroleptic agents and employment of different salts and metabolites of a known active is within the skill of the artisan and therefore obvious. (Page 4, paragraph 3 of the Office Action).

Applicants respectfully submit that these assertions are unfounded. Moreover, they are contrary to what was shown in the art prior to the invention. For example, it was reported that neither ziprasidone sulfone nor ziprasidone sulfoxide likely contributes to the antipsychotic activity of ziprasidone. Prakash, C. *et al.*, Drug Metab. Dispos., 25(7):863-872 (1997). It was also reported that ziprasidone metabolites in general are not active at the D_2 and 5-HT_{2A} receptor sites. Ereshefsky, L., J. Clin. Psych., 57(suppl. 11):12-25 (1996). *See*

also, page 2, line 27 to page 3, line 10 of the specification. Therefore, the cited art would have provided no teaching, motivation or suggestion to those of ordinary skill in the art to make the claimed invention.

Because the Examiner's assertion that one of ordinary skill in the art would have been motivated to employ ziprasidone metabolites does not appear to be based on factual evidence obtained from the prior art, Applicants respectfully request that the rejection of claims 10-15 be withdrawn. *See, In re Sang-Su Lee*, 277 F.3d 1338, 1343-4 (Fed. Cir. 2002).

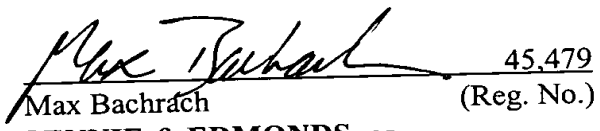
Conclusion

All of the claims are believed to be in condition for allowance. Should the Examiner disagree, Applicants respectfully request a telephonic or personal interview to address any remaining issues.

No fee is believed to be due for this submission. However, if any fees are necessary for the entry of this submission or to avoid abandonment of this application, please charge such fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

Date: August 14, 2002



45,479
(Reg. No.)

Max Bachrach
PENNIE & EDMONDS LLP
1667 K Street, N.W.
Washington, D.C. 20006
(202) 496-4400

For: Anthony M. Insogna (Reg. No. 35,203)
PENNIE & EDMONDS LLP
1155 Avenue of the Americas
New York, New York 10036-2711
(212) 790-9090